

## 510(k) Summary

JUN - 8 2009

**510(k) Type:** Traditional  
**Submission Date:** 05.05.2009

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**Predicate device name and 510(k) number:** Nordic Image Control and Evaluation (nordicICE) Software, K082441

**Modified Device Name:** nordicICE Software  
**Device Common Name:** PACS  
**Basis for Submission:** Device modification with new software

**Classification Regulation:** 892.2050

**Class:** II  
**Panel:** Radiology  
**Product Code:** LLZ

**Trade/Proprietary Name:** nordicICE Software

## Device Description

nordicICE – Nordic Image Control and Evaluation software – is a medical viewing, analysis, and processing package developed with a view to ease of use and high performance on a standard Windows platform. The software provides a wide range of basic image processing and manipulation functions, in addition to comprehensive functionality for dynamic image analysis and processing/display of functional MRI (fMRI) data. The main user of the program will be imaging professionals who need to visualize and analyze images taken primarily from a MRI system.

## Intended Use

nordicICE is an image processing software package to be used by trained professionals including but not limited to physicians and medical technicians. The software runs on a standard "off-the-shelf" PC workstation and can be used to perform image viewing, processing and analysis of medical images. Data and images are acquired through DICOM compliant imaging devices and modalities.

nordicICE provides both viewing and analysis capabilities of functional and dynamic imaging datasets acquired with MRI or other relevant modalities, including blood oxygen level dependent (BOLD) fMRI, diffusion weighted MRI (DWI) / fiber tracking and dynamic analysis.

**BOLD fMRI:** BOLD analysis is used to highlight small magnetic susceptibility changes in the human brain in areas with altered blood-flow resulting from neuronal activity.

**DWI/Fiber Tracking:** Diffusion analysis is used to visualize local water diffusion properties from the analysis of diffusion-weighted MRI data. Fiber tracking utilize the directional dependency of the diffusion to display the white matter structure in the brain.

**Dynamic Analysis:** Dynamic analysis is used for visualization and analysis of dynamic imaging data of the brain, showing properties of changes in contrast over time where such techniques are useful or necessary.

## Identification of Change to Unmodified Device

The nordicICE software offers comprehensive functionality for dynamic image analysis and visualization, where signal changes over time are analyzed to determine various modality dependent functional parameters. Now this functionality has been extended to include dedicated analysis methods and visualization tools for dynamic contrast enhanced imaging data (from MRI or CT) where a bolus injection of a contrast agent material results in a temporal change in the signal intensity. This dynamic change in signal intensity is used to calculate functional parameters related to tissue flow (perfusion) and tissue blood volume as well as leakage (due to capillary permeability) of the injected contrast material from the intravascular- to the extracellular space. The functionality has been implemented as additional software modules to the existing device, and is referred to as:

- **nordicICE Perfusion Module** – Calculation of parameters related to tissue flow (perfusion) and tissue blood volume.
- **nordicICE DCE Module** – Calculation of parameters related to leakage of injected contrast material from intravascular- to extracellular space.

The changes summarized above are the only modification made to the nordicICE software.

### **Statement of Substantial Equivalence**

To summarize, the modified nordicICE software is found substantial equivalent to the previously cleared device. The modified software only includes additional modules which extend the current functionality used for dynamic image analysis and the indications for use for the modified nordicICE software have remained unchanged.

### **Summary of Testing**

The nordicICE software has been tested for function and safety and fulfills all requirement specifications.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN - 8 2009

Mr. Chandana G. Bhandari  
Quality Manager  
NordicImagingLab AS  
Møllendalsveien 65C  
N-5009 Bergen  
NORWAY

Re: K090546

Trade/Device Name: Nordic Image Control and Evaluation (nordicICE) Software

Regulation Number: 21 CFR 892.2050

Regulation Name: Picture archiving and communications system

Regulatory Class: II

Product Code: LLZ

Dated: May 5, 2009

Received: May 14, 2009

Dear Mr. Bhandari:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

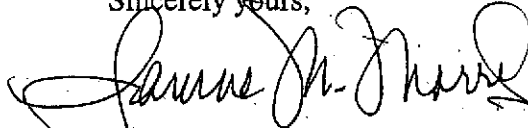
21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

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You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Janine M. Morris  
Acting Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K090546

Device Name: Nordic Image Control and Evaluation (nordicICE) Software

### Indications for Use:

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Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal and  
Radiological Devices

510(k) Number

K090546

NordicImagingLab AS  
nordicICE Software

Indications for Use  
Attachment 2